Decision Memo for Liver Transplantation (CAG-00053N)

Decision Summary

Since the exclusion for hepatitis B was originated, the state-of-the-art in medicine has changed such that the outcome for these transplant patients with hepatitis B has improved significantly. The development of antiviral drugs and the long-term passive immunization have improved the outcomes by reducing the occurrence of reinfection. Recent medical literature suggests that liver transplantation improves outcomes in patients with hepatitis B. Therefore, HCFA is removing the coverage exclusion for hepatitis B.

The literature to date still does not indicate that outcomes for patients with liver cancer improve with transplantation. We will continue to review literature on this topic in the future. Should the literature support removing the exclusion for liver cancer, we will do so. Until that time, the exclusion remains.

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Decision Memo

TO: File: Liver Transplantation
CAG Control No. 00053N

FROM:

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RE: National Coverage Decision

DATE: December 2, 1999

This memo outlines the background behind the existing liver transplantation coverage exclusion of hepatitis B and the rationale for removing this coverage exclusion. In addition, this memo explains why the coverage exclusion for malignancies will not be removed at this time.

Background

Liver transplantation in adults may be necessary for survival when a patient develops severe end-stage liver disease. The United Network for Organ Sharing has identified the primary diagnoses associated with liver transplantation. This list is included as Attachment A. As of November 11, 1999, 14,262 persons are waiting for a liver transplant.[1] In 1998, 4886 livers were transplanted.[2]

According to the American Liver Foundation, hepatitis B is the sixth most common indication for liver transplantation.[3] The hepatitis B may either be the underlying cause of the end-stage liver disease or a concomitant infection. Because of the past experience with recurrence of hepatitis B, transplantation in individuals with hepatitis B is controversial.

Medicare first began to cover adult liver transplantation on April 12, 1991. The policy was published in the Federal Register (56 FR 15006) on April 12, 1991, as a final notice and based upon a recommendation from the Office of Health Technology Assessment (OHTA) of the Public Health Service. The functions of OHTA are currently performed by the Agency for Health Care Policy and Research. Coverage of adult liver transplantation was limited to the following conditions: primary biliary cirrhosis; primary sclerosing cholangitis; postnecrotic cirrhosis, hepatitis B surface antigen negative; alcoholic cirrhosis; Alpha-1 antitrypsin deficiency disease; Wilson's disease; or primary hemochromatosis.

The existing coverage policy found in section 35-53 of the Coverage Issues Manual provides coverage for adult liver transplantation "when performed on beneficiaries with end stage liver disease, other than hepatitis B or malignancies...." This broader coverage became effective July 15, 1996. When the current policy was implemented, there was still insufficient evidence that transplantation improved the outcomes of patients with hepatitis B or liver cancer. Liver transplantation for hepatitis B was questioned because of an 80%-100% chance of reinfection of the allograft by the hepatitis B virus and reduced long term survival. The hepatitis B infection in the graft may be accelerated and may progress to cirrhosis or fibrosing cholestatic hepatitis which rapidly progresses to liver failure, retransplantation, or death.

Recent Evidence

Recent developments in molecular diagnostics and antiviral therapies have dramatically improved the prevention of recurrent viral infection after liver transplantation in recipients infected with hepatitis B.[4] For example, one promising antiviral agent appears to be lamivudine. [5],[6] Long-term passive immunization and dosing to achieve and maintain hepatitis B antibody levels in the serum also appears to improve the survival rates of liver transplants in patients with hepatitis B.[7]

There is only very limited information suggesting the possibility of improved outcomes of transplantation for patients with liver cancer. Until additional evidence becomes available, we do not believe that the evidence base is sufficient to modify the current coverage exclusion for liver cancer.

Conclusion and Decision

Since the exclusion for hepatitis B was originated, the state-of-the-art in medicine has changed such that the outcome for these transplant patients with hepatitis B has improved significantly. The development of antiviral drugs and the long-term passive immunization have improved the outcomes by reducing the occurrence of reinfection. Recent medical literature suggests that liver transplantation improves outcomes in patients with hepatitis B. Therefore, HCFA is removing the coverage exclusion for hepatitis B.

The literature to date still does not indicate that outcomes for patients with liver cancer improve with transplantation. We will continue to review literature on this topic in the future. Should the literature support removing the exclusion for liver cancer, we will do so. Until that time, the exclusion remains.

Attachment A: UNOS 1998 Scientific Registry and Organ Procurement Transplant Network Annual Report, Appendix G: Organ Specific Diagnosis Categories

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1 UNOS web site, December 1, 1999.

2 UNOS OPTN/Scientific Registry data as of September 14, 1999.

3 Vierling JM, Teperman LW, Brownstein AP. Hepatitis B: An Appropriate Indication for Liver Transplantation - Results and Recommendations of a Hepatitis B Liver Transplant Symposium, American Liver Foundation, December 1998.

4 Dodson SF, Issa S, Bonham A. Liver Transplantation for Chronic Viral Hepatitis, *Surgical Clinics of North America* 1999; 79(1): 131-145.

5 Dodson *et al*.

6 Nery JR, Weppler D, Rodriguez M, Ruiz P, Schiff ER, Tzakis AG. Efficacy of Lamivudine in Controlling Hepatitis B Virus Recurrence after Liver Transplantation, *Transplantation* 1998; Vol 65, 1615-1621.

7 Terrault NA, Zhou S, Combs C, Hahn JA, Lake JR, Roberts JP, Ascher NL, Wright TL. Prophylaxis in Liver Transplant Recipients Using a Fixed Dosing Schedule of Hepatitis B Immunoglobin, *Hepatology* 1996; December: 1327-1333.

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